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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/04, 2/24 — A1

(11) International Publication Number: **WO 00/12027**

(43) International Publication Date: 9 March 2000 (09.03.00)

(21) International Application Number: PCT/US99/19686

(22) International Filing Date: 26 August 1999 (26.08.99)

(30) Priority Data:

09/140,935	27 August 1998 (27.08.98)	US
09/218,765	22 December 1998 (22.12.98)	US

(71) Applicant: ENDONETICS, INC. [US/US]; Suite 102, 5830 Oberlin Drive, San Diego, CA 92121 (US).

(72) Inventors: JOHNSON, George, M.; 1841 Derby Drive, Santa Ana, CA 92705 (US). KILCOYNE, John; 5265 Caminito Exquisito, San Diego, CA 92130 (US). KELLEHER, Brian, S.; 11146 Weatherwood Terrace, San Diego, CA 92131 (US).

(74) Agent: ALTMAN, Daniel, E.; Knobbe, Martens, Olson and Bear, LLP, 16th floor, 620 Newport Center Drive, Newport Beach, CA 92660 (US).

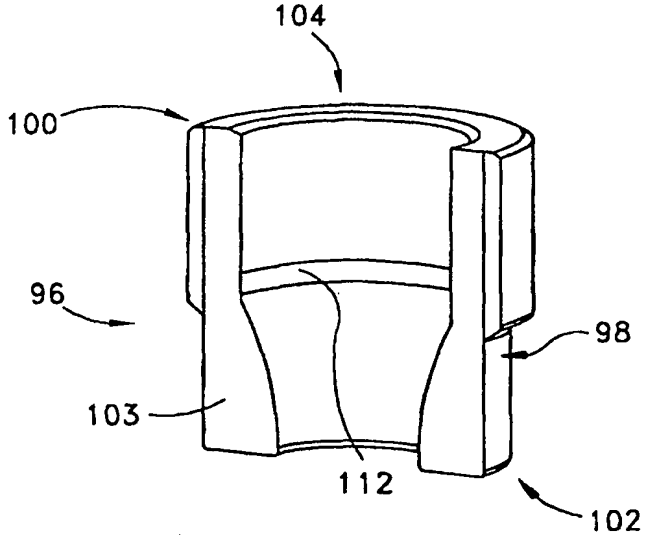
(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), DM, EE, EE (Utility model), ES, FI, FI (Utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: LOWER ESOPHAGEAL BULKING DEVICE

(57) Abstract

Disclosed is a prosthetic gastro–esophageal bulking device (96), for transesophageal implantation to treat gastro–esophageal reflux disease. The bulking device (96) comprises an anchor (108) for attachment to the wall of the esophagus, and a bulking device (110) for cooperating with residual lower esophageal sphincter function to inhibit gastric reflux. Related devices, and methods are also disclosed.



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LOWER ESOPHAGEAL BULKING DEVICE

Background of the Invention

This invention relates to a prosthetic valve or bulking prosthesis for non-invasive insertion in the vicinity of the lower esophagus sphincter (LES).

Gastroesophageal reflux is a physical condition in which stomach acids reflux, or flow back up from the stomach into the esophagus. Frequent reflux episodes (two or more times per week), may result in a more severe problem known as gastroesophageal reflux disease (GERD). Gastroesophageal reflux disease is the most common form of dyspepsia, being present in approximately 40% of adults in the United States or an intermittent basis and some 10% on a daily basis. Dyspepsia or heartburn, is defined as a burning sensation or discomfort behind the breastbone or sternum and is the most common symptom of GERD. Other symptoms of gastroesophageal reflux disease include dysphasia, odynophagia, hemorrhage, water brash, and pulmonary manifestations such as asthma, coughing or intermittent wheezing due to acid aspiration. Dyspepsia also may mimic the symptoms of a myocardial infarction or severe angina pectoris.

Factors that are believed to cause GERD include: transient lower esophageal sphincter relaxations, decreased LES resting tone, delayed stomach emptying, and ineffective esophageal clearance. One primary cause of gastroesophageal reflux disease is the lack of competency of the lower esophageal sphincter. The lower esophageal sphincter, or valve, is comprised of smooth muscle located at the gastroesophageal (GE) junction.

At rest, the LES maintains a high-pressure zone between 10 and 30 mm Hg above intragastric pressure. Upon deglutition, the LES relaxes before the esophagus contracts, allowing food to pass through into the stomach. After food passes into the stomach, the LES contracts to prevent the stomach contents and acids from regurgitating into the esophagus. The mechanism of the LES opening and closing is influenced by innervation via the vagus nerve and hormonal control of gastrin and possibly other gastrointestinal hormones.

Complications of GERD include esophageal erosion, esophageal ulcer, and esophageal stricture. Stricture formation often results from prolonged exposure of the esophageal mucosa to acid reflux. The most common clinical manifestation of stricture is dysphasia. Unlike dysphasia from non-strictured esophageal reflux, dysphasia caused by stricture is a progressive disorder in that the size of a bolus which can pass into the stomach progressively becomes smaller. Prolonged acid exposure to esophageal mucosa may lead to a more serious condition known as Barrett's esophagus. Barrett's esophagus is defined as the replacement of normal squamous epithelium with abnormal columnar epithelium. Barrett's esophagus or clinical change in tissue structure is clinically important not only as a marker of severe reflux, but also as a potential precursor to cancer of the esophagus.

Current methods of treating gastroesophageal reflux disease consist of life style changes such as weight loss and avoidance of certain foods that may exacerbate the symptoms of GERD. Avoidance of excessive bending combined with elevation of the head of the bed helps prevent nocturnal reflux. While avoidance of exacerbating factors may be helpful, there is relatively little data supporting the efficacy of lifestyle modification alone for the treatment of GERD.

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There are a variety of different techniques designed for the treatment of less serious cases of GERD. Medications have been used for years with varying results. Conventional antacids (TUMS , ROLAIDS) produce short term relief, but often result in negative side effects including diarrhea and constipation. H2 blocker receptor antagonists (Cimetidine, Ranitidine) are relatively more effective in controlling symptoms than antacids, but result in treatment of the symptoms and not the underlying cause of the disease. The more powerful secretory inhibitors, the proton pump inhibitors (Omeprazole, Lansoprazole) are much more effective than H2 blockers, but are expensive and may, in the long term, produce negative side effects. The only alternative to these conventional forms of medical treatment, which must be taken constantly at great cost, are the surgical methods of preventing reflux.

There are numerous reflux operations available which perhaps reflect the inadequacy of any one procedure to totally control the problem. The most commonly performed operation, Nissen fundoplication, may be effective, but is often complicated by stricture formation or gas bloat syndrome. A laparoscopic Nissen approach has been developed, adding another dimension of difficulty, with long term results still in question. In addition, a percutaneous laparoscopic technique has been developed as can be seen, for example, in the United States Patent No. 5,006,106 to Angelchik. Minimally invasive techniques, such as transesophageal implantation of a prosthetic valve have been attempted. See, for example, United States Patent No. 4,846,836 to Reich. The existing forms of medical and surgical treatment for gastroesophageal reflux all have shortcomings.

In view of the foregoing, and notwithstanding the various efforts exemplified in the prior art, there remains a need for a non-invasive prosthetic valve and deployment methodology for transesophageal implantation into the vicinity of the lower esophageal sphincter. Preferably, the valve permits both antegrade and retrograde flow and is removable or replaceable with minimal trauma to the surrounding tissue.

Summary of the Invention

There is provided in accordance with one aspect of the present invention, a method of treating gastroesophageal reflux disease. The method comprises the steps of providing a prosthetic gastroesophageal bulking device, having a tissue ingrowth surface and a bulking element thereon. The bulking device is positioned at about the base of the esophagus, and the tissue ingrowth surface is brought into contact with the wall of the esophagus or cardia to permit cellular ingrowth through the wall of the ingrowth surface.

In accordance with another aspect of the present invention, a prosthetic gastroesophageal bulking device for implantation in the vicinity of the lower gastroesophageal sphincter is provided. The bulking device comprises a flexible body, having a proximal end and a distal end. A tissue ingrowth surface is provided on the body, for contacting tissue in the vicinity of the lower esophageal sphincter and permitting cellular ingrowth therein. A bulking element is provided on the body for cooperating with the LES to inhibit gastric reflex.

Preferably, the prosthetic gastroesophageal bulking device comprises a tubular structure. The tissue ingrowth surface comprises a porous material such as a porous PTFE. In one embodiment, the tissue ingrowth surface and bulking

element comprise a unitary structure. In another embodiment, the tissue ingrowth surface and the bulking element comprise at least two components connected together.

In accordance with a further aspect of the present invention, there is provided a prosthetic gastroesophageal bulking structure, for implantation in a patient. The bulking structure comprises a tubular body, having a proximal end and a distal end. At least one bulking element is provided on the tubular body. The tubular body further comprises an anchor such as a tissue ingrowth surface thereon, for contacting tissue and permitting cellular ingrowth therein. In one embodiment, the bulking element comprises a tubular wall. Alternatively, the bulking element comprises one or more axially extending bulking elements such as strips.

Further features and advantages of the present invention will become apparent from the detailed description of preferred embodiments which follow, when considered together with the attached drawings and claims.

Brief Description of the Drawings

Figure 1 is a schematic view of a removable gastroesophageal valve assembly in accordance with the present invention, positioned at about the junction between the esophagus and the stomach.

Figure 2 is a side elevational view of the valve assembly of Figure 1.

Figure 3 is an exploded perspective view of the valve, anchor, and temporary tubular support in accordance with one embodiment of the present invention.

Figures 4a and 4b show schematic views of an alternate gastroesophageal valve assembly in accordance with the present invention.

Figure 5 is a side elevational perspective view of a further alternate gastro-esophageal valve in accordance with the present invention.

Figure 6 is a schematic representation of an alternate embodiment of the present invention.

Figure 7 is a schematic representation of an alternate embodiment of the present invention.

Figure 8 is a side elevational cross section of a lower esophageal bulking device in accordance with the present invention.

Figure 9 is a side elevational cross section of an alternate lower esophageal bulking device of the present invention.

Figure 10 is a side elevational cross section of a further embodiment of a lower esophageal bulking device in accordance with the present invention.

Figure 11 is a side elevational view of two nontubular bulking strips in accordance with the present invention.

Detailed Description of the Preferred Embodiment

Referring to Figure 1, there is illustrated a schematic representation of the stomach 10 and a portion of the lower esophagus 12. The esophagus 12 extends through the diaphragm 14, below which the esophagus 12 communicates with the interior of the stomach 10. A prosthetic gastroesophageal valve assembly 16 in accordance with the present invention is illustrated at about the junction between the lower esophagus 12 and the stomach 10.

Although the anatomy illustrated in Figure 1 is generally normal, except for the improperly functioning native lower gastroesophageal sphincter, the present invention is also useful in patients having lower esophageal abnormalities, such as a hiatal hernia. In this condition, a portion of the wall of the stomach 10 extends upwardly through the diaphragm 14 and herniates superiorly to the diaphragm 14. The existence of a hiatal hernia or other abnormality in the lower esophagus may affect the implanted location of the valve assembly 16, but will generally not disqualify a patient otherwise treatable with the valve assembly 16 of the present invention.

Referring to Figure 2, the valve assembly 16 generally comprises an anchor 18 and a valve 20. The anchor 18 can comprise any of a variety of structures useful for securing the valve 20 to the lower portion of the esophagus. For example, any of a variety of tubular structures which can be secured to the esophagus or cardia through the use of hooks, pins, sutures, adhesives, staples, clips, tacks and/or radially outwardly directed force can be used. Alternatively, any of a variety of non-tubular structures, such as axially extending attachment strips or connectors, can be utilized to attach the valve assembly 20 to the esophageal wall or cardia. Such attachment strips can be secured to the esophageal wall or other internal anatomical structure using any of a variety of connectors, such as hooks, pins, sutures, adhesives, staples, tacks, clips and others which will be apparent to those of skill in the art.

In a preferred embodiment, however, the anchor 18 comprises a flexible tubular sleeve adapted to permit cellular ingrowth to provide the primary long term fixation against both proximal and distal axial movement. Suitable materials include polytetrafluoroethylene, polyethylene terephthalate, polyester, polyurethane, silicone and other materials which will be apparent to those of skill in the art in view of the present disclosure. As used herein, "distal" shall refer to a location closer to the stomach and "proximal" shall refer to a location closer to the mouth.

The anchor 18 is preferably porous to permit cellular ingrowth of the lining of the esophagus to inhibit axial migration. In addition, since ingrowth of the mucosal lining in one embodiment goes through the sleeve, the resulting anchor will be lined with living tissue. This ingrown cellular layer may also protect the artificial material of the anchor from physical damage due to passing material.

Porosity in the range of from about 2μ to about 100μ or greater may be desirable to facilitate ingrowth. In one embodiment of the invention, the anchor 18 comprises a tubular PTFE extrusion, having a wall thickness of about 0.4 mm, a porosity of about 20μ, an axial length of about 1.5 cm, and a diameter of about 2 cm. Suitable dimensions for any particular application can be readily determined by those of ordinary skill in the art in view of the disclosure herein.

The anchor 18 is generally characterized by a proximal end 22, a distal end 24 and a lumen 26 extending therethrough. Preferably, the lumen is substantially free of obstructions, to optimize the cross-section of the esophageal flow path. The axial length of the anchor 18 is divided into two functional components. A proximal attachment zone 23 is sufficiently long to permit attachment between the anchor 18 and the esophagus. The length of the attachment zone 23 may vary depending upon the attachment mode. For example, a relatively shorter attachment zone 23 may be utilized where supplemental attachment structures such as sutures, hooks, pins, staples, tacks, clips or adhesives are intended to be left in place to retain the valve assembly 16 within the lower esophagus or cardia. Alternatively, a relatively longer

attachment zone 23 may be desirable where cellular ingrowth is the primary or exclusive long-term mode of attachment. In general, an axial length of the attachment zone 23 will typically be greater than about 1 cm, preferably greater than about 1.5 cm, and may be greater than about 2 cm in an embodiment intended to be restrained by cellular ingrowth.

A distal portion of the anchor 18 includes a flexible skirt portion 25, for extending between the attachment portion 23 and a valve or a releasable connector 28. The skirt portion 25 permits a flexible connection between the attachment portion 23 of the anchor which is secured to the esophageal wall or cardia and the releasable connector 28 which is secured to the valve 20. The skirt portion also permits suspending the valve in the stomach, if desired. Flexibility in the skirt between the valve 20 and the attachment point to the esophagus or cardia desirably accommodates natural movement (i.e., radial contraction and expansion) of the esophagus or cardia as well as any residual native esophageal sphincter function, without compromising the attachment between the anchor 18 and the wall of the esophagus or cardia. The use of a flexible tubular skirt portion of at least about 1 cm and preferably 2 cm or more in length is believed to permit reciprocal contraction and expansion of the lower esophagus from diameters as large as 20 mm or more down to substantially closed without disrupting the cellular ingrowth or other attachment at the attachment zone 23.

The valve 20 may be either permanently or releasably connected to the anchor 18. Permanent attachment can be accomplished in a variety of ways such as by integrally forming the valve 20 with the anchor 18. Alternatively, a separately formed valve 20 can be attached to the anchor 18 using adhesives and/or mechanical attachment structures such as sutures, clips, metal loops or other interference fit or mechanical junctions.

The distal end 24 of the anchor 18 is alternatively provided with a releasable connector 28 in a releasable valve embodiment. Preferably, the valve 20 is provided with a corresponding proximal connector 30 which contains a complementary surface structure to the releasable connector 28 on the distal end 24 of anchor 18. In the illustrated embodiment, the releasable connector 28 comprises a radially outwardly extending annular recess 32 having a greater internal cross-sectional area than the cross-sectional area of the distal aperture 38 at the distal end of the releasable connector 28. In this manner, the proximal connector 30 on valve 20 can be resiliently deformed (e.g., compressed) to fit through the distal aperture 38 and expand within the annular recess 32, thereby providing a removable interference fit between the valve 20 and the anchor 18. The foregoing structure advantageously also permits both the implantation of the valve within the releasable connector 28 and removal of the valve from the releasable connector 28 either proximally through the central lumen 26 of anchor 18 or distally through the distal aperture 38.

In the embodiment illustrated in Figure 2, an annular restraining loop 34 is molded within or attached to the wall of the distal end 24 of anchor 18, to resist or limit radial expansion of the distal aperture 38. Loop 34 may comprise any of a variety of materials, such as metal wire, suture, mono-filament or multi-filament polymeric fibers, and the like, as will be appreciated by those of skill in the art in view of the disclosure herein. Loop 34 may be molded within a distal portion 24 of the anchor 18, or attached thereto such as by sutures, adhesives, weaving through the material of anchor 18, or other techniques known in the art. Loop 34 may also be merely a thickened section of the wall of anchor 18. In general, the inside diameter of aperture 38 and consequent diameter of loop 34 is selected to cooperate with the outside diameter of

proximal connector 30 to provide a sufficient interference fit to permit implantation and extraction of the valve 20 from the releasable connector 28 as desired, but resist proximal or distal movement of the valve 20 with respect to the anchor 18 under normal anatomical forces.

In one embodiment of the present invention, the anchor 18 has an inside diameter within the range of from about 15 mm to about 20 mm, and the distal aperture 38 has an inside diameter at least about 5% and preferably as much as 10% or more smaller than the inside diameter of the anchor 18. This provides one or more interference surfaces 39 facing generally in the proximal direction for providing an interference fit with the valve 20. The interference surface 39 is preferably an annular surface, surrounding the aperture 38. Interference surface 39 may face in a proximal direction, or be radially outwardly inclined in the proximal direction as illustrated. Alternatively, interference surface 39 may be provided along a series of discrete elements circumferentially spaced around the aperture 38.

The proximal connector 30 of valve 20 has a maximum diameter which is preferably at least about 1 or 2 mm greater than the diameter of aperture 38 and, more preferably, is at least 3 to 5 mm or more greater in diameter than the diameter of the aperture 38. The proximal connector 30 is configured in a manner that produces an interference surface 42 which either faces in a distal direction, or is inclined radially inwardly in the distal direction as illustrated. In this manner, the interference surface 42 of the proximal connector 30 engages the interference surface 39 on releasable connector 28 to removably restrain the valve 20 within the releasable connector 28.

The extent of the interference necessary to achieve a useful retention force can be readily determined through routine experimentation by one of ordinary skill in the art in view of the materials utilized for the releasable connector 28 and proximal connector 30. For example, a relatively larger interference surface area will be desirable for highly flexible or elastic materials such as silicone. More rigid materials and/or the use of reinforcement structures such as wire loop 34 will enable a smaller total interference surface area as will be apparent to those of skill in the art.

Any of a variety of alternative interference fit or snap fit structures can be adapted for use at the junction between the valve 20 and the anchor 18 as may be desired for a particular application. For example, radially outwardly extending annular flanges on the valve 20 may snap fit within one or more annular recesses on the anchor 18. Alternatively, anchor 18 may be provided with radially inwardly extending projections or annular flanges to be received within a radially inwardly extending slot or slots on the proximal connector 30 of valve 20.

In the illustrated embodiment, the valve 20 comprises one or more proximal connectors 30 and two or more moveable or flexible leaflets 36. Although the present invention will be discussed primarily in terms of a two-leaflet or three-leaflet valve, any of a wide variety of valve structures can be removably coupled to the anchor 18 in accordance with the present invention and accomplish the objectives of the prosthetic gastroesophageal valve. The specific valving mechanism can thus be varied without departing from the spirit of the present invention. In general, the valve 20 preferably has a structure which permits as large as possible an open cross-sectional area so that it will not obstruct the flow of material from the esophagus into the stomach.

In one embodiment, the valve 20 comprises a three-leaflet valve injection molded or otherwise formed from silicone or polyurethane, and containing a tapered wall such that the distal end (coaptive edges) of each leaflet 36 has a lesser wall thickness than the proximal (superior) ends of the leaflets 36. In addition, a thickened annular band is preferably provided in the region of the proximal connector 30, to increase the resistance to radial collapse. One or more internal support structures such as annular wire loops may be integrally molded within or attached to the proximal end of the valve 20 to increase the radial strength of the proximal connector 30. At least one radiopaque marker is also included, to permit visualization as is understood in the art.

Preferably, the valve 20 permits both forward flow from the esophagus into the stomach, as well as limited reverse flow. One structure for enabling controlled reverse flow is upper valve 36 disclosed in United States Patent No. 4,846,836 to Reich, entitled Artificial Lower Gastrointestinal Valve, the disclosure of which is incorporated by reference in its entirety herein. Other provisions for reverse flow will be discussed *infra*, in connection with Figures 4 and 5.

Referring to Figures 4a and 4b, there is illustrated an alternate valve 46 permanently or removably secured to an anchor 18 in position within the distal esophagus 12 (or cardia) at about the junction with the stomach 10. The valve 46 comprises a generally conically-shaped body 48 having a forward flow opening 51 and a reverse flow opening 52. The forward flow opening 51 is provided with a movable first valve cover 50 illustrated in a closed orientation in Fig. 4a and in an open orientation in Fig. 4b. The valve cover 50 may be biased towards a closed position to obstruct reverse flow through aperture 51. However, forward flow of material from the esophagus into the stomach displaces the valve cover 50 to permit forward flow.

The reverse flow opening 52 is provided with a second valve cover 53 illustrated in a closed orientation in Fig. 4b. Valve cover 53 will open in response to retrograde pressure in excess of a predetermined break pressure for permitting reverse flow. Although the hinge side of valve cover 53 is illustrated at the lower edge of the reverse flow opening 52, the hinge may alternatively be located at the upper edge of opening 52 similar to the illustrated valve cover 51. Each of the valve covers 51 and 53 may be integrally molded with the housing 48, or separately formed and attached thereto, as may be desired in the view of the preferred manufacturing technique. The entire housing 48 including valve covers 51 and 53 may be injection molded from any of a variety of flexible biocompatible materials such as, for example, silicone or polyurethane. The cross-sectional area of the forward flow aperture 50 and reverse flow aperture 52 can be varied as desired, depending upon the clinical objective.

In accordance with another embodiment of the present invention (Fig. 7) there is provided a hybrid valve structure which includes both the leaflet primary valve construction of Figures 1-3 and the reverse flow valve construction of the embodiment of Figure 4. Thus, forward flow through the valve is accomplished by forward pressure opening two or three or more coaptive valve leaflets. One or two or three or more of the leaflets are provided with a reverse flow aperture such as aperture 52 in Figure 4. The reverse flow aperture is additionally provided with a valve cover such as valve cover 53 illustrated in Figure 4.

Referring to Figure 7, valve 84 includes at least two and preferably three leaflets 86, separated by coaptive edges 88 as is well known in the heart valve art. The leaflets 86 are connected to a base 90, which may be permanently or removably connected to an anchor as has been discussed. Alternatively, the coaptive leaflets 86, base 90 and anchor (not illustrated) can be integrally formed as a unitary device. One or more reverse flow ports 92 are provided on valve 84. Preferably, two or three or more reverse flow ports 92 are provided. Each reverse flow port is provided with a valve cover 94, for inhibiting forward flow but permitting reverse flow through the flow port 92.

Referring to Figure 5, there is illustrated a further embodiment of a valve useful in the present invention. The valve 56 comprises an annular attachment ring 58 having a central aperture 60 therethrough. A compound flapper 62 comprises a forward flow component 64 and a reverse flow component 66. Forward flow is accomplished by displacing both the reverse flow component 66 and forward flow component 64 in a distal direction, thereby opening central aperture 60 to permit forward flow. Reverse flow is accomplished by seating component 64 against annular ring 58, and permitting reverse flow component 66 to pivot in a proximal direction thereby opening reverse flow path 68.

The valve of Figure 5 can be integrally molded from suitable biocompatible materials, such as silicone, polyurethane, or other materials known in the art. Alternatively, two or more components can be separately manufactured and assembled together to produce the valve 56. For example, forward flapper component 64 and reverse component 66 can be manufactured as an integral unit and subsequently attached to the proximal ring 58 such as through the use of a pin or other hinged attachment structure. Annular ring 58 may be provided with internal or external support structures, such as an annular wire as has been discussed, to enhance the structural integrity of the removable connection between the valve 56 and the anchor 18.

Referring to Figure 3, the valve assembly of Figure 2 is shown in an exploded fashion, along with a tubular support 40 for use during cellular ingrowth into and/or through the wall of the anchor 18. In general, the anchor 18 may have relatively little structural integrity, and is desirably held in place against the esophageal wall for a sufficient period of time to permit cellular ingrowth. In one embodiment, the tubular support 40 is thereafter removable such as by radial compression, and retraction into a retrieval catheter. Depending upon the construction of tubular support 40, the support 40 may alternatively be disassembled and withdrawn into a retrieval device. As a further alternative, the tubular support 40 is constructed of a bioabsorbable material, such that the tubular support 40 dissolves or is otherwise disintegrated after a suitable ingrowth period of time. Absorption or disintegration of the self removable embodiment may occur as a function of the passage of time in the intended use environment, or may be catalyzed or facilitated such as by the application of an activating agent which initiates or accelerates degradation of the material of the tubular support 40. The use of a tubular support 40 may not be necessary, however, in an embodiment in which the anchor 18 is tacked, sutured, or otherwise mechanically secured to the esophageal wall.

Tubular support 40 preferably comprises an elongate self-expandable tubular wire cage, adapted to be compressed into a relatively low cross-sectional profile such as for implantation and capable of self-expansion upon release from a deployment device within the anchor 18 at the attachment site. One example of a self-expandable tubular support

which may be adapted for use in the present invention is that disclosed in United States Patent No. 5,282,824 to Gianturco, entitled Percutaneous Stent Assembly, the disclosure of which is incorporated in its entirety herein by reference. Although the Gianturco structure is disclosed in the context of a coronary stent, this structure may be readily scaled up to suitable dimensions for use in the lower esophagus as will be apparent to those of skill in the art in view of the disclosure herein.

Any of a variety of alternate structures can be utilized for tubular support 40. Self-expandable tubular supports can be configured from any of a variety of materials well known in the cardiovascular stent and graft arts, such as the stainless steel and Nitinol. Alternatively, tubular support 40 can be designed for implantation and expansion using an expansion device such as a balloon catheter as will be understood by those of skill in the art.

In one embodiment, the tubular support 40 is additionally provided with a plurality of radially outwardly extendable hooks or barbs, which can be pressed into the mucosal lining to minimize the risk of migration during the cellular ingrowth stage. Expandable tubular wire supports having hooks or barbs to minimize axial migration are disclosed in the context of abdominal aortic aneurism grafts, for example, in United States Patent No. 5,562,728 to Lazarus, et al., the disclosure of which is incorporated in its entirety herein by reference. Attachment barbs may be adapted to extend radially outwardly into the esophageal mucosa automatically upon expansion of the tubular support 40. Alternatively, the attachment barbs may be radially outwardly advanceable in response to manipulation of a control or manually exerted pressure from a tacking device, graspers or other tool which may be transesophageally positioned within the tubular support 40, such as through the working channel of an endoscope.

Referring to Figure 6, there is disclosed an alternate embodiment of the present invention. A prosthetic LES valve 70 generally comprises a support 72, connected to a valve 74. Support 72 comprises a radially expandable support structure such as a wire mesh or wire coil such as may be adapted from the coronary artery stent or abdominal aortic aneurysm graft arts. The wire coil may comprise any of a variety of materials, such as stainless steel, which may be radially expanded following deployment from a tubular catheter. Alternatively, memory metals such as Nitinol may be utilized as will be understood by those of skill in the art.

Valve 74 may comprise any of a variety of valves previously disclosed herein. In the illustrated embodiment, Valve 74 comprises a three leaflet valve, having a first coaptive leaflet 76, a second coaptive leaflet 78 and a third coaptive leaflet 80. Three leaflet valves are well understood in the heart valve arts, and can be used on the embodiment of Figure 6 or any other embodiment disclosed herein.

Preferably, the support 72 such as a coil stent is surrounded by an outer tubular sleeve 82. Outer sleeve 82 provides a tissue ingrowth surface thereon, and may comprise materials disclosed elsewhere herein such as porous PTFE or Dacron.

In accordance with one implantation method of the present invention, the lower esophageal wall and/or cardia is denuded or injured such as by the use of a mechanical abrasion device and/or chemical exposure. Bipolar or monopolar radio frequency electrodes (e.g. electrocautery) may also be utilized to injure the esophageal lining. In general, the

esophageal wall in the lower esophagus is in the area of 3 to 4 mm thick. Preferably, the mucosal layer is injured or removed down to a depth sufficient to ensure adequate ingrowth into the anchor 18.

The valve assembly 16 including a self-expandable tubular support 40 is preferably preloaded into a tubular introducer. In general, the introducer comprises an elongate tubular body preferably having an outside diameter of no more than about 5 to about 15 mm or smaller. The valve assembly 16 is preferably radially compressed within the central lumen of the tubular introducer, such as at the point of manufacture. The valve assembly 16 may include the valve 20, for deployment in a single operation. Alternatively, the introducer may be preloaded with the anchor 18 and self expandable tubular support 40 for deployment in a first step, with the valve 20 to be subsequently deployed within the releasable connector 28 of the previously implanted anchor 18 as a second step. The tubular introducer comprises an axially moveable platform which may be distally advanced within the tubular housing to deploy the valve assembly 16 therefrom. The introducer is advanced transesophageally (or laparoscopically or percutaneously) to the deployment site, and the valve assembly and tubular support 40 are deployed. Upon deployment of the tubular support from the deployment device, the tubular support 40 radially outwardly expands to compress the anchor 18 against the esophageal wall.

Following deployment of the valve assembly 16 at the attachment site, the tubular support 40 may be left in place for a sufficient ingrowth period of time and then removed from the patient. The inventor contemplates removal of the tubular support within the range of from about 2 to 6 weeks following implantation. Alternatively, the tubular support may be left in place within the anchor 18.

As will be appreciated in view of the foregoing removable valve disclosure, the valve 20 may be removed from the anchor 18 while leaving the anchor 18 in position within the esophagus. This may be accomplished, for example, by retracting the valve 20 within a tubular sheath positioned transesophageally within the anchor 18. A replacement valve may thereafter be deployed within the releasable connector 28. The anchor 18 may also be removed, if desired, such as by ablation or denuding of the ingrown tissue using chemical, electrical or mechanical abrading techniques. Alternatively, the anchor 18 may be excised from the esophageal wall such as by cutting with any of a variety of cutting tools adaptable for use through the working channel of an endoscope.

Referring to Figure 8, there is disclosed an elevational cross sectional schematic view of a lower esophageal bulking device in accordance with another aspect of the present invention. The bulking device 96 comprises a main body 98 having a proximal end 100 and a distal end 102. The main body 98 has at least one esophageal wall contacting attachment surface 101 and at least one bulking element 103.

In general, the attachment surface 101 can be on the bulking element 103 or can be directly or indirectly attached to the bulking element 103 so that the bulking element 103 will be positioned in the esophagus and retained in position by attachment of the attachment surface 101 to the esophageal wall or other tissue. In use, the bulking element 103 is preferably positioned within the area of the lower esophageal sphincter, to inhibit gastric reflux which might otherwise have occurred due to an incomplete closure of the sphincter. Due to the irregular cross sectional configuration of

the closed sphincter, the cross sectional configuration of the bulking element 103 can take on any of a wide variety of shapes including but not limited to those specific embodiments disclosed herein.

The tissue attachment surface 101 may include any of the attachment anchors or structures disclosed previously herein. In one embodiment, the attachment surface 101 preferably facilitates tissue ingrowth from the esophageal wall, to maintain the bulking element 103 in a predetermined location within or about the esophageal sphincter. This may be accomplished by providing the tissue attachment surface 101 with a porous structure, such as porous PTFE or other materials which will be known to those of skill in the art.

The attachment surface 101 may be additionally or alternatively provided with any of a variety of tissue retention structures such as hooks or barbs. Additional securing structures or materials may be used alone or in addition to the hooks, barbs or tissue ingrowth surfaces, such as tacks, sutures, staples, tissue adhesives or others which will be understood by those of skill in the art in view of the disclosure herein.

In one embodiment, the main body 98 comprises a tubular wall defining a lumen 104 therethrough. The body 98 includes an anchor or attachment zone 108 and a bulking zone 110. The attachment zone 108 may be positioned proximally of the bulking zone 110, as illustrated, and comprises a tissue ingrowth surface 101 thereon. The tissue ingrowth surface 101 may extend throughout the length of the attachment zone 108 and bulking zone 110, or be limited to the attachment zone 108. Alternatively, the separate attachment zone 108 can be omitted, and the tissue ingrowth surface is provided concentrically around the bulking zone 110.

In one embodiment, the bulking device 96 comprises a non-tubular structure such as a strip, which contains an attachment zone 108 for attachment to the esophageal wall and a bulking zone 110 for assisting the function of the lower esophageal valve. In the non-tubular embodiment, the strip shaped bulking device 96 preferably has a relatively thin radial direction cross section at a proximal end thereof and a gradually increasing or relatively large cross section near a distal portion thereof. A tissue ingrowth surface is preferably provided on one side of the bulking device 96, either throughout the entire axial length of the device, or throughout at least the proximal portion thereof.

For example, referring to Figure 11, a bulking device comprises one or two or three or more (schematically illustrated) generally axially extending strips 97. Each strip 97 preferably comprises a relatively thin attachment zone 108 and a relatively thicker or greater cross section bulking zone 110. The one or more strips 97 are aligned generally parallel with the longitudinal axis of the esophagus. Where two or more bulking strips 97 are utilized to improve LES function, the strips 97 may be equally spaced around the circumference of the LES. The use of multiple strips 97 without rigid interconnection may permit the LES to radially expand to a greater degree than the tubular bulking devices described above, such as to permit bolus passage.

In one embodiment of the invention, the strip 97 has an axial length of about 2 cm to about 4 cm, and a width of about 0.5 cm to about 1.0 cm. The thickness of the strip in the attachment zone 108 is about 0.4 mm, and the thickness of the strip in radial direction in the bulking zone is about 0.5 cm to about 1 cm. In general, the axial length of the strip 97 embodiment will be at least about 2 cm and preferably within the range of from about 2 cm to about 4 cm. The bulking

zone 110 will preferably be at least about 1 cm in length. The structure and materials for the embodiment illustrated in Figure 11 may be similar to strip shaped portions cut from tubular embodiments disclosed elsewhere herein, and optimal dimensions and materials can be determined through routine experimentation by one of skill in the art in view of the disclosure herein.

In the embodiment illustrated in Figure 8, the bulking device 96 comprises a generally cylindrical body 98, having an outside diameter which is approximately the same as the inside diameter of the human esophagus, normally in the range of from about 1.8 cm to about 2.2 cm for adults, and an axial length within the range of from about 2 cm to about 4 cm. The wall thickness in the attachment zone 108 is generally sufficiently thick to support an attachment surface, and maintain that surface in contact with the esophageal wall. In one embodiment, the attachment zone 108 comprises a thin flexible membrane of porous PTFE, having a wall thickness of about 0.016 inches. However, wall thicknesses in the attachment zone 108 up to as much as .08 inches or greater can be utilized, depending upon the intended characteristics of the bulking device 96.

One advantage of a thin walled attachment 108 is the ability to achieve cellular ingrowth and possibly cellular overgrowth along the radially inwardly facing surface of the attachment zone 108. Excessive wall thickness may inhibit the ability to achieve cellular overgrowth, and may also restrict flow in the esophagus and/or increase the likelihood that material passing through the esophagus will dislodge the bulking device 96 from its implanted position. Implantation of a device utilizing a thin walled porous PTFE attachment zone 108 or other thin flexible attachment zone 108 will likely need to be accompanied by a temporary fixation structure during an initial cellular ingrowth period of time, as has been discussed elsewhere herein.

The axial length of the attachment zone 108 can vary from 0 (where there is no separate attachment zone 108 and the cellular ingrowth surface is provided on the radially outwardly facing wall of the bulking zone 110) to as much as 1 cm or 2 cm or greater, depending upon the desired axial retention force and permissible intrusion into the esophagus. In one embodiment, the attachment zone 108 is approximately 1 cm in length and the bulking zone 110 is in the range of from about 1 to about 3 cm in length.

The attachment zone 108 is separated from the bulking zone 110 in the illustrated embodiment by a transition 112. Distally of the transition 112, the wall thickness in the bulking zone 110 is relatively thicker than the wall thickness in the attachment zone 108. For example, the wall thickness in the bulking zone 110 in one embodiment of the invention progressively increases from about 0.4 mm to about 10 mm.

In addition to occupying a predetermined volume, the bulking zone 110 is preferably both soft and spongy. Soft structure minimizes the risk of trauma to adjacent tissue. By spongy it is intended that the material expands when nothing is passing through the LES, but will compress to no more than about 4 mm and preferably no more than about 2 mm in radial thickness during swallowing. Preferably, following swallowing, the bulking zone 110 will rebound back to facilitate the LES function.

In general, the desired wall thickness of the bulking zone will be dependent upon lumen diameter and the extent of LES disfunction. Devices produced in accordance with the present invention can be rated according to their bulking area, which represents the total cross sectional area the device will occupy within the sphincter.

For example, an LES having a relaxed, open diameter of 2 cm has a cross sectional area of 3.14 cm^2. A 25% bulking function could be accomplished by providing a bulking device 96 having a total cross sectional area in the bulking zone of about 0.785 cm^2. That bulking area may represent the area of a unitary strip type device, having a generally oval or rectangular cross section (e.g. 0.443 cm x 1.772 cm) which is adapted to extend axially through the esophagus. Alternatively, that bulking area can be distributed as the sum of the cross sectional area of the wall thickness of a tubular wall. For example, a wall having a thickness of 0.125 cm and a diameter of 2 cm has a total cross sectional area of about 0.785 cm^2. In actual devices intended for use in human adults having a LES diameter of 2 cm, the total bulking area in a cross sectional plane intended to be positioned at about the LES will generally be within the range of from about 20% to about 80% of the relaxed LES diameter.

The bulking device 96 of Figure 8 can be manufactured as a unitary or multi-component structure in any of a variety of ways as will be appreciated by those of skill in the art in view of the disclosure herein. For example, the bulking device 96 may be molded in a single piece of biocompatible foam material such as silicone foam or polyurethane foam, or may be cut from a block of such foam. Such foam parts can be made with a skin on the inner surface to reduce wear from food abrasion, while maintaining the porous foam outer surface to facilitate ingrowth. Alternatively, the device 96 of Figure 9 and 10 can be made by attaching an outer sleeve of porous material such as expanded polytetrafluoroethylene (ePTFE) or other ingrowth material to the device of Figure 8 by bonding the two materials together. For example, if expanded PTFE is used a PTFE surface etching step may be used prior to bonding with a silicone base glue, or, alternatively, the process of gluing by simultaneously compressing and heating the stack-up of foam, glue and ePTFE can be used. The non-tubular embodiment of the present invention, as shown in Figure 11, can be fabricated with any of the same processes described above for the embodiments shown in Figures 8, 9 and 10.

An alternate embodiment of the bulking device 96 is illustrated in Figure 9. In the embodiment of Figure 9, the attachment zone 108 is provided with a separate attachment layer 114. Attachment layer 114 preferably comprises a material which facilitates cellular ingrowth from the mucosal wall of the esophagus. Such materials include, for example, polytetrafluoroethylene, polypropylene or polyester as has been discussed above. The attachment layer 114 may be secured to the attachment zone 108 of the bulking device 96 in any of a variety of manners, such as by solvent bonding, thermal bonding, adhesives and others as will be apparent to those of skill in the art in view of the disclosure herein.

A further embodiment of the lower esophageal bulking device is illustrated in Figure 10. Referring to Figure 10, the bulking device 96 comprises an outer element 98 having a radially inwardly facing bulking component 116 attached thereto. In the illustrated embodiment, the outer element 98 comprises a tubular wall, and the bulking element comprises a tubular bulking structure secured to the radially inwardly facing surface of tubular wall 98. Alternatively, the bulking structure 116 could be positioned on the radially outwardly facing surface of tubular wall 98. Attachment of the bulking

structure 116 to the element 98 can be accomplished in any of a variety of manners as will be understood by those of skill in the art in view of the disclosure herein, such as by adhesives, thermal bonding, solvent bonding and the like.

In any of the foregoing embodiments, the main body 98 may comprise either an integrally formed wall, or a wall fabricated from two or more components or surface treatments. For example, the tissue contacting surface 101 is preferably provided with a microporous structure to facilitate tissue ingrowth. However, the radially inwardly directed surface preferably has lower friction, to facilitate the movement of material through the esophagus without dislodging the bulking device 96. Surface friction on the interior wall of the bulking device may be reduced in any of a variety of manners, such as by coatings, surface treatments, or the provision of a laminate layer. For example, an interior liner of PTFE or other material having a relatively smaller (e.g., three micron) porosity than the tissue ingrowth surface may be provided. Chemical or thermal treatments may also be used to form a low friction skin on the surface of many materials. Alternatively, silicone can be laminated to the surface.

In one embodiment, the tubular wall 98 and bulking element 103 are integrally formed from a foam such as a polyurethane. The exterior surface of the foam is provided with a substantially nonporous skin, either throughout or at least on the surface which contacts material passing through the esophagus.

Preferably, the bulking device 96 will exert a small radial direction bias, such that it will provide pressure to match that of a healthy native sphincter, without creating enough pressure to cause necrosis, atrophy or erosion. In this manner, the bulking device 96 can cooperate with any residual function of the LES, to minimize the occurrence of reflux.

Although the foregoing invention has been disclosed in terms of certain preferred embodiments, other specific embodiments can be constructed in view of the disclosure herein without departing from the spirit and scope of the present invention. Accordingly, the scope of applicant's invention is to be determined by reference to the attached claims, which are not limited to any of the particular embodiments disclosed herein.

WHAT IS CLAIMED IS:

1. A prosthetic gastroesophageal bulking device for implantation in the vicinity of the lower gastroesophageal sphincter, comprising:

a flexible body, having a proximal end, and a distal end;

a tissue ingrowth surface on the body for contacting tissue in the vicinity of the lower gastroesophageal sphincter and permitting cellular ingrowth therein; and

a bulking element on the body for cooperating with the LES to inhibit gastric reflux.

2. A prosthetic gastroesophageal bulking device as in Claim 1, wherein the body comprises a tubular structure.

3. A prosthetic gastroesophageal bulking device as in Claim 1, wherein the bulking element is an elongate strip.

4. A prosthetic gastroesophageal bulking device as in Claim 1, wherein the tissue ingrowth surface comprises PTFE.

5. A prosthetic gastroesophageal bulking device as in Claim 1, wherein the tissue ingrowth surface and bulking element comprise a unitary structure.

6. A prosthetic gastroesophageal valve as in Claim 1, wherein the tissue ingrowth surface and bulking element comprise at least two components connected together.

7. A prosthetic gastroesophageal bulking structure, for implantation in a patient, comprising:

a tubular body, having a proximal end, and a distal end;

at least one bulking element on the tubular body;

wherein the tubular body comprises a tissue ingrowth surface thereon for contacting tissue and permitting cellular ingrowth therein.

8. A prosthetic gastroesophageal bulking device as in Claim 7, wherein the tissue ingrowth surface comprises PTFE.

9. A prosthetic gastroesophageal bulking device as in Claim 7, wherein the bulking element comprises a tubular element.

10. A prosthetic gastroesophageal bulking device as in Claim 7, wherein the bulking element is a nontubular element attached to the tubular body.

11. A prosthetic gastroesophageal bulking device as in Claim 7, wherein the bulking device comprises an elongate strip.

12. A prosthetic gastroesophageal valve, for implantation in the vicinity of the lower gastroesophageal sphincter, comprising:

a flexible anchor, having a proximal end, a distal end, and a lumen extending therethrough;

a releasable connector on a distal end of the anchor;

a valve having a proximal connector thereon;

wherein the valve is removably connected to the anchor by a releasable engagement between the proximal connector on the valve and the releasable connector on the anchor.

13. A prosthetic gastroesophageal valve as in Claim 12, wherein the anchor comprises a tubular polymeric membrane.

14. A prosthetic gastroesophageal valve as in Claim 13, wherein the anchor comprises PTFE.

15. A prosthetic gastroesophageal valve as in Claim 12, wherein the valve comprises a first valved forward flow path and a second valved reverse flow path.

16. A prosthetic gastroesophageal valve as in Claim 15, wherein the first forward flow path comprises at least two flexible coaptive leaflets.

17. A prosthetic gastroesophageal valve as in Claim 12, further comprising a tubular support within the anchor, to press the anchor against the adjacent tissue.

18. A prosthetic gastroesophageal valve, for implantation in a patient, comprising:

an anchor, having a proximal end, and a distal end;

a valve on the anchor;

wherein the anchor comprises a tissue ingrowth surface thereon for contacting tissue and permitting cellular ingrowth therein.

19. A prosthetic gastroesophageal valve as in Claim 18, wherein the anchor comprises a tubular polymeric membrane.

20. A prosthetic gastroesophageal valve as in Claim 19, wherein the anchor comprises PTFE.

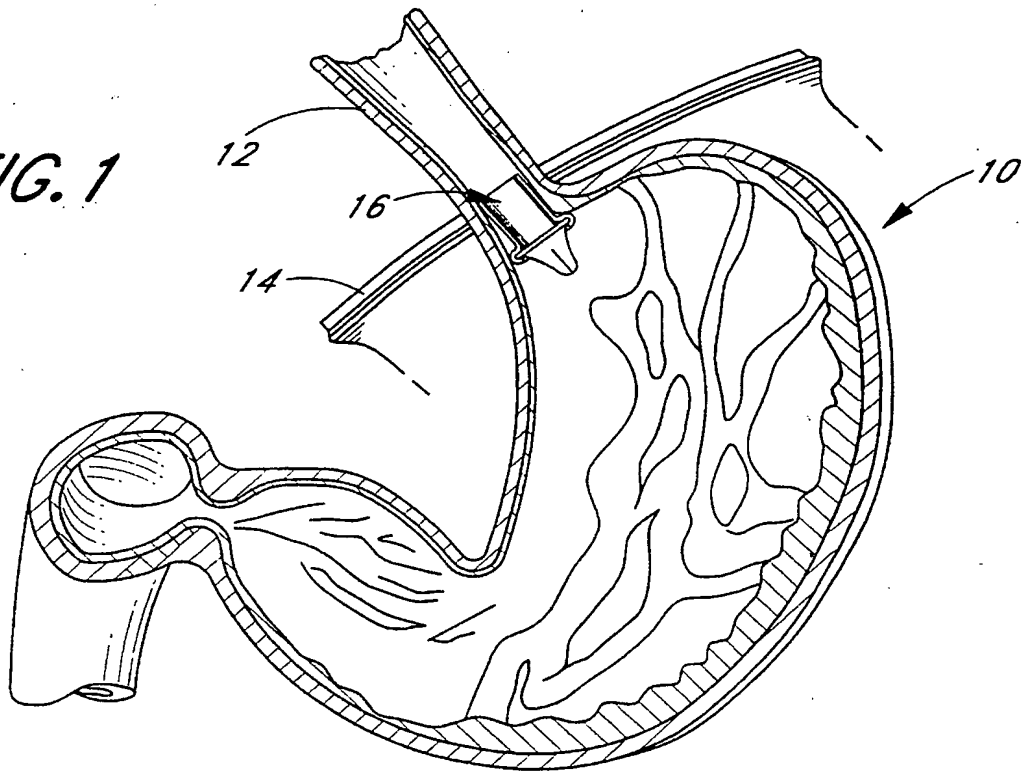
21. A prosthetic gastroesophageal valve as in Claim 18, wherein the valve comprises a first valved forward flow path and a second valved reverse flow path.

22. A prosthetic gastroesophageal valve as in Claim 21, wherein the first forward flow path comprises at least two flexible coaptive leaflets.

23. A prosthetic gastroesophageal valve as in Claim 18, wherein the anchor and valve comprise a unitary structure.

24. A prosthetic gastroesophageal valve as in Claim 18, wherein the valve and anchor comprise at least two components connected together.

FIG. 1



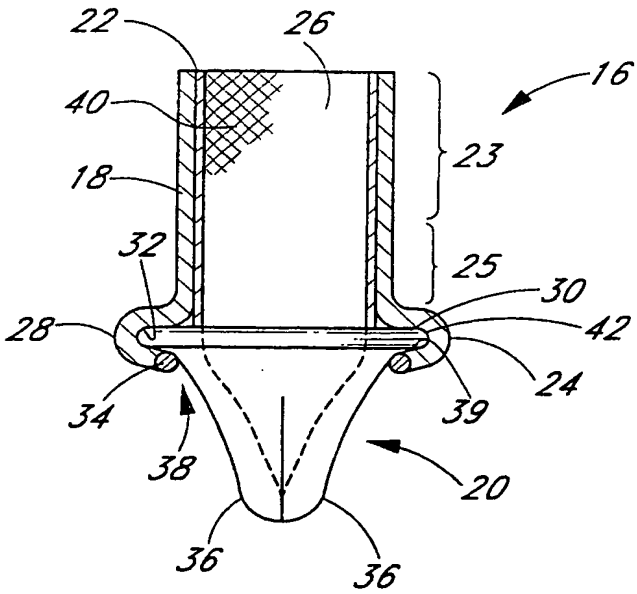


FIG. 2

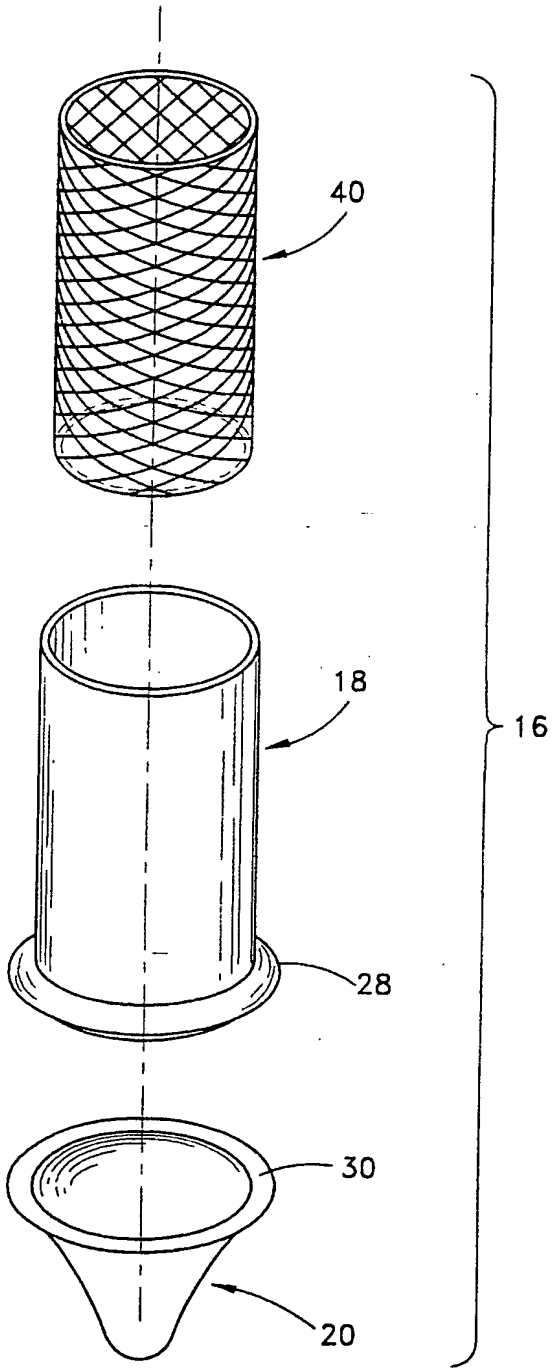


FIG. 3

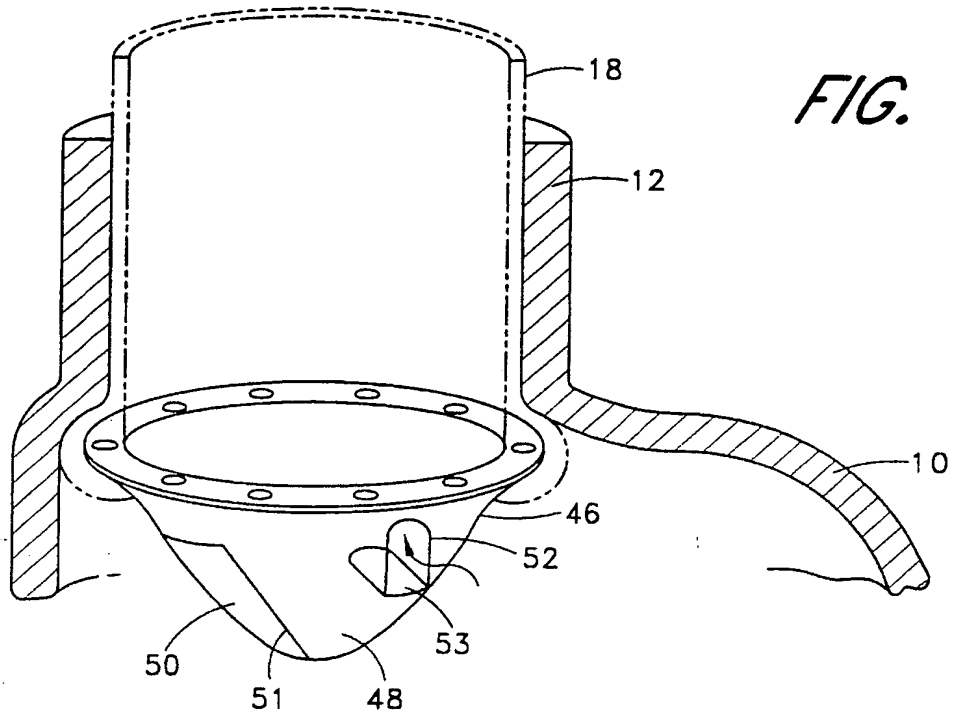


FIG. 4A

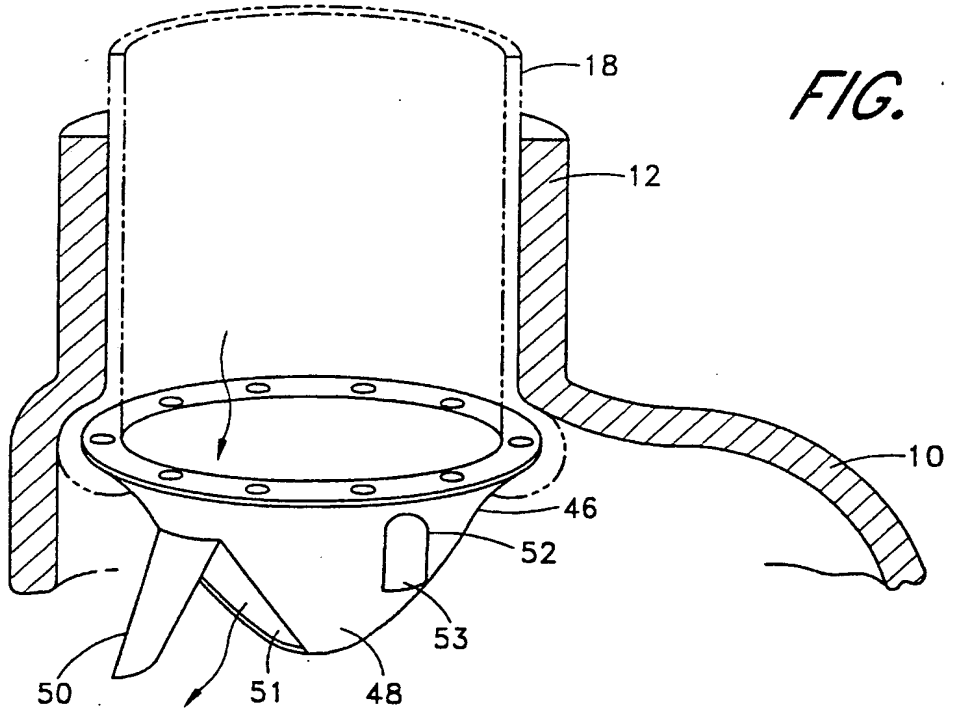
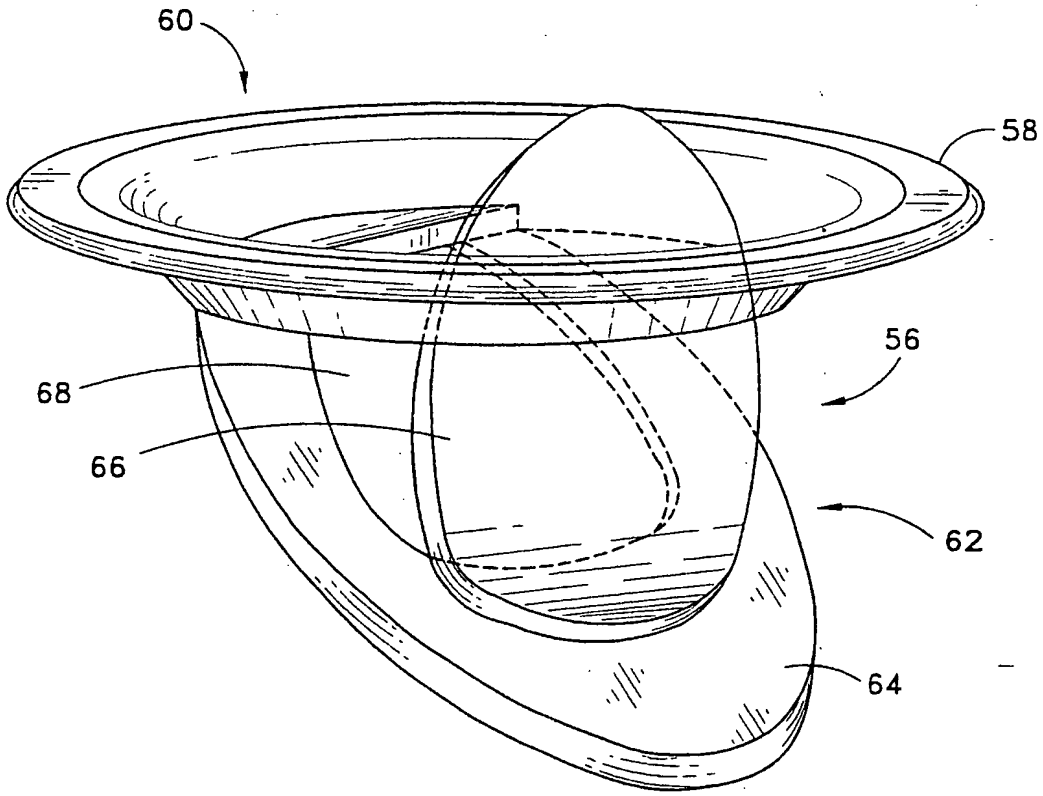


FIG. 4B

FIG. 5



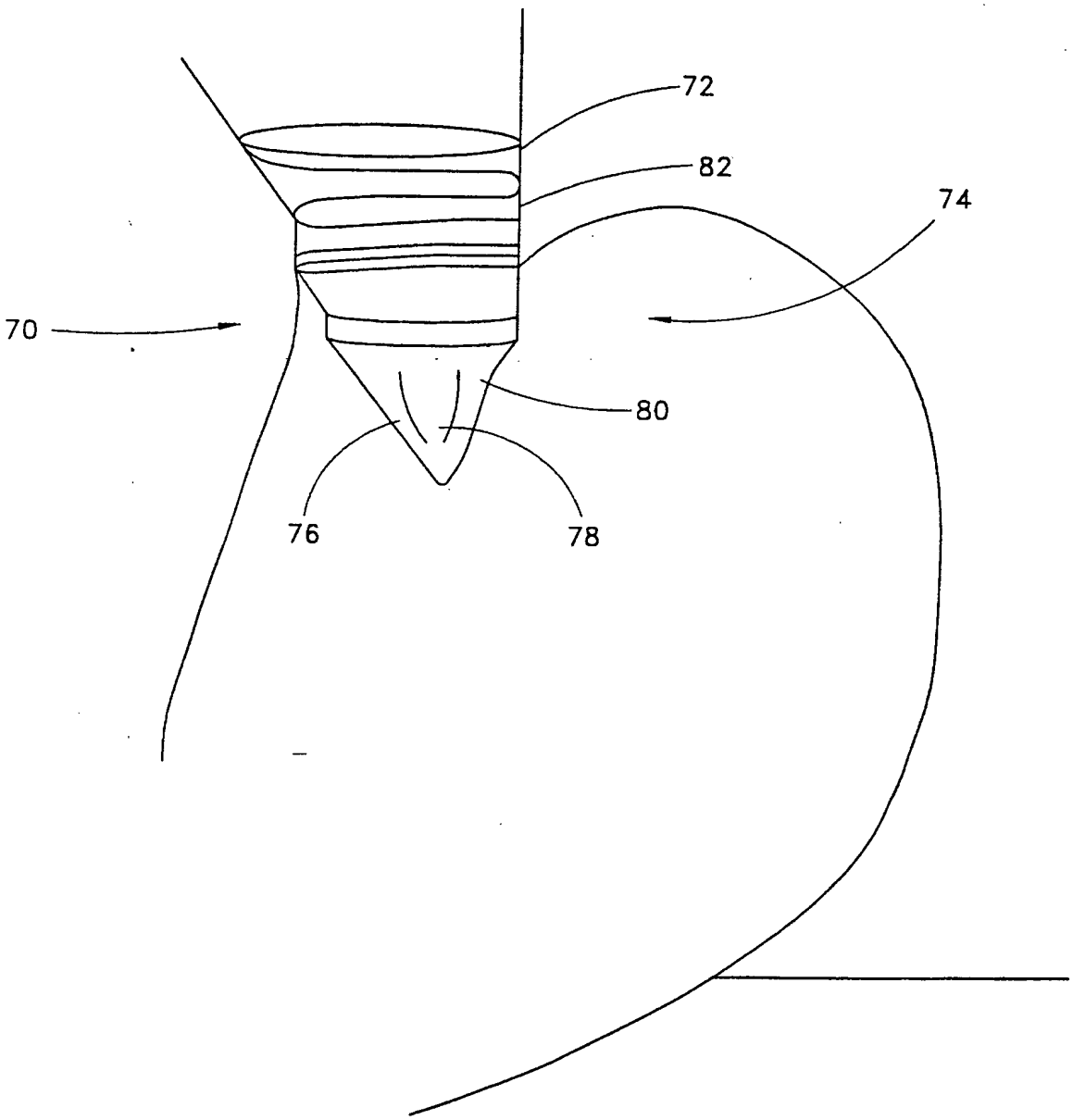


FIG. 6

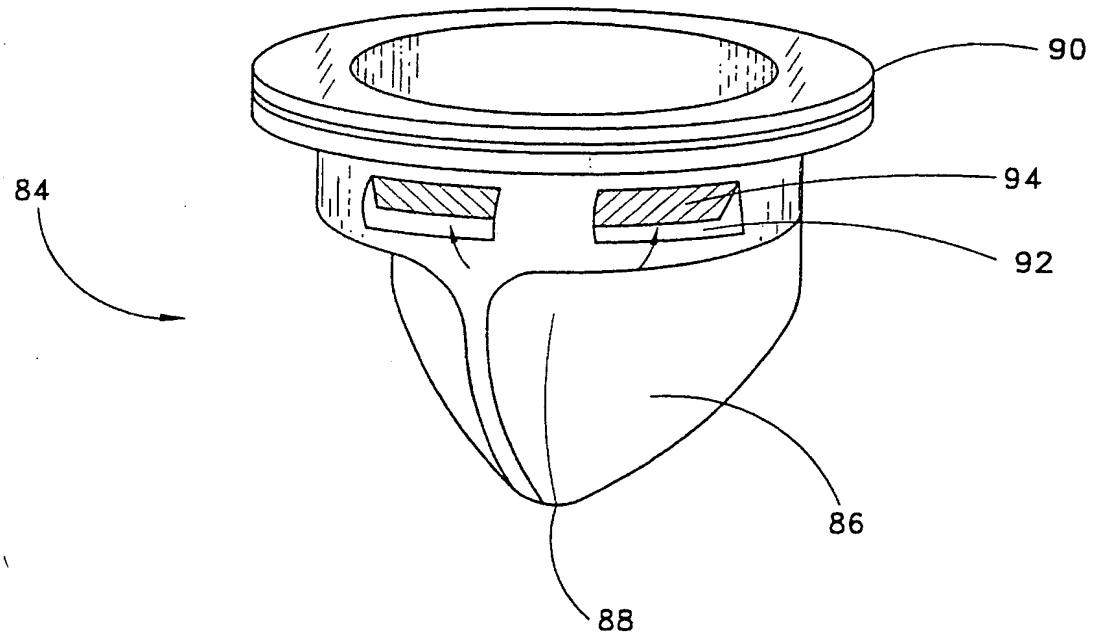


FIG. 7

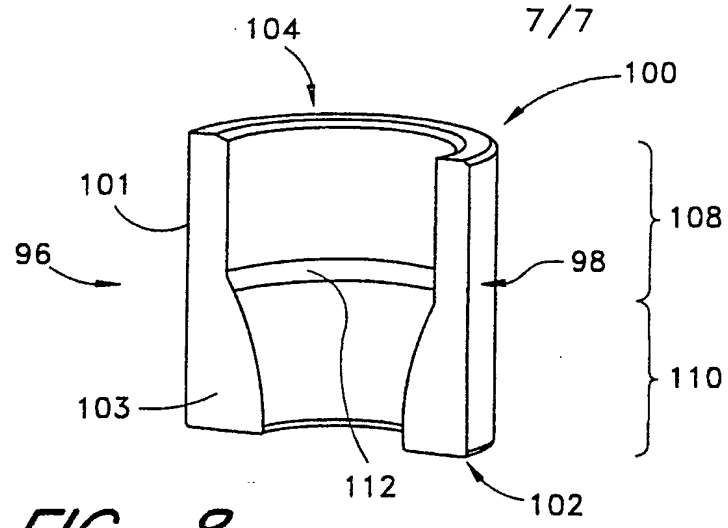


FIG. 8

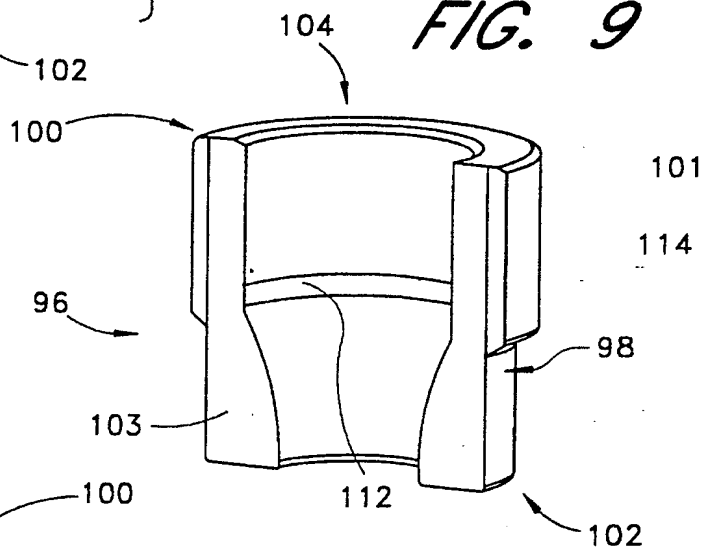


FIG. 9

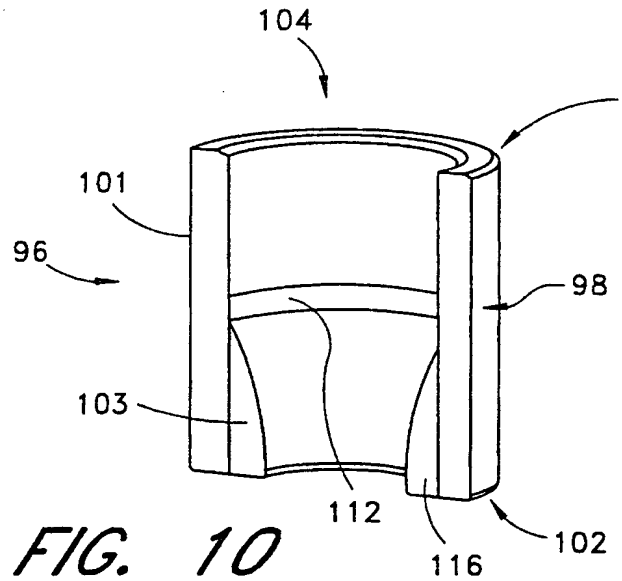


FIG. 10

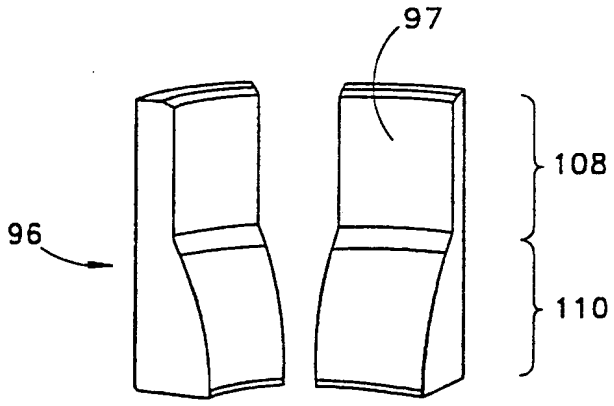


FIG. 11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/19686

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61F 2/04, 24
US CL :623/02, 12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/02, 12

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WEST
EAST

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,314,473 A (GODIN) 24 May 1994, elements 9 and 10.	1-5, 7-11
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Y		6
X	US 5,411,552 A (ANDERSEN et al.) 02 May 1995, valve (6).	12-14, 17-20,
X	US 4,846,836 A (REICH) 11 July 1989, Fig. 2.	18-20, 23
X	US 4846,836 A (Reich) Jul. 11, 1989, see Fig. 2.	18-20 and 23

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
09 NOVEMBER 1999	15 DEC 1999
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer ALVIN STEWART Telephone No. (703) 305-0277

Form PCT/ISA/210 (second sheet)(July 1992)★